Anritsu

Quicca Pharma

Overall Quality Management and Control System for Pharmaceutical Products

QUICCA Pharma monitors and manages production data, ensuring data integrity.

Background

FDA (the U.S. Food and Drug Administration) issued final part 11 regulations in March 1997 and 21 CFR Part 11 became effective in August 1997.
In 2019, the revision of GMP (Good Manufacturing Practice) was made and requirements for data integrity were added.

In view of the trends of globalization, it is necessary to implement electronic data management system and data integrity complied with Part 11.

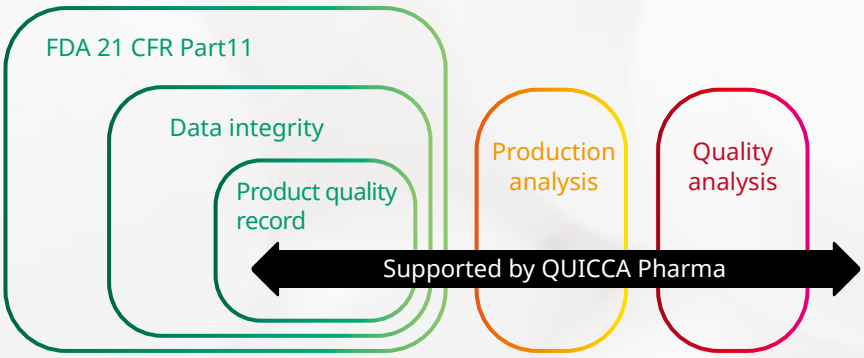
In the pharmaceutical manufacturing, quality management of products is being handled by KPP (Key Process Parameter) and CPP (Critical Process Parameter) under PQS (Pharmaceutical Quality System).
Operation depending on the common sense of operator and manager cannot fully prevent human errors such as incorrect and missing entering, falsification of data with malicious intent.

QUICCA Pharma with advanced features for data integrity provides audit trail, data encryption and decryption to ensure the reliability of pharmaceutical product quality.

Data from the inspection systems will be stored in one centralized location, enabling a quick search of specific information. Analyzing data from multiple inspection systems can enhance productivity. For instance, by measuring OEE (Overall Equipment Effectiveness), you can gain an accurate understanding of overall production efficiency, helping you match the analytical capacity of equipment demands.

In Pharma 4.0, the value of data is more enhanced.

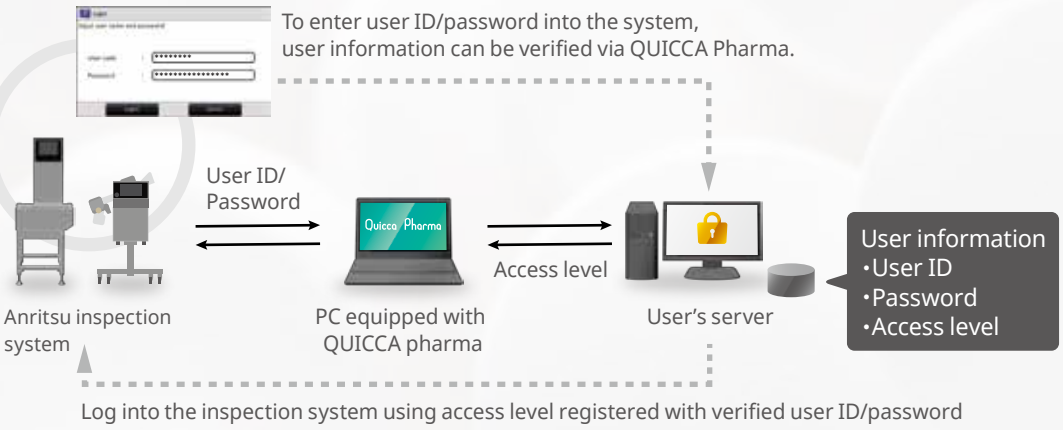
With QUICCA Pharma, the credibility of quality management and enhanced productivity are achieved, supporting for total quality management on your production line.



QUICCA Pharma Offers Comprehensive Features for FDA 21 CFR Part 11 Compliance.

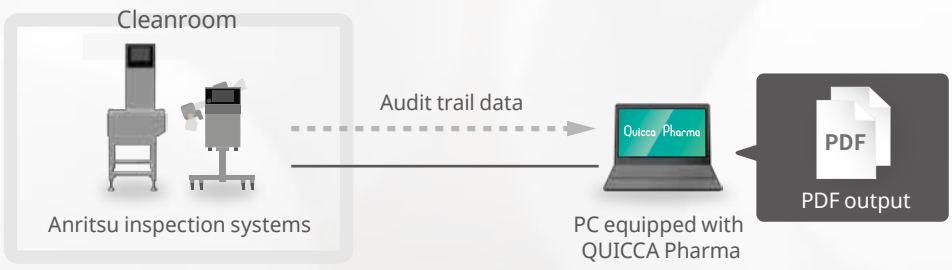
Centralized Data Management for User Authentication

With QUICCA Pharma, user information can be managed in one centralized location using the Windows Active Directory function. It means operators can easily log in to multiple inspection systems using the Windows user information, and this makes it possible to quickly trace operation history per each operator.



Audit Trail

The history of operations and actions related to production and results of operation check are internally recorded. The data can be used to monitor fraudulent activity or incorrect operation and analyze the cause of such activity.

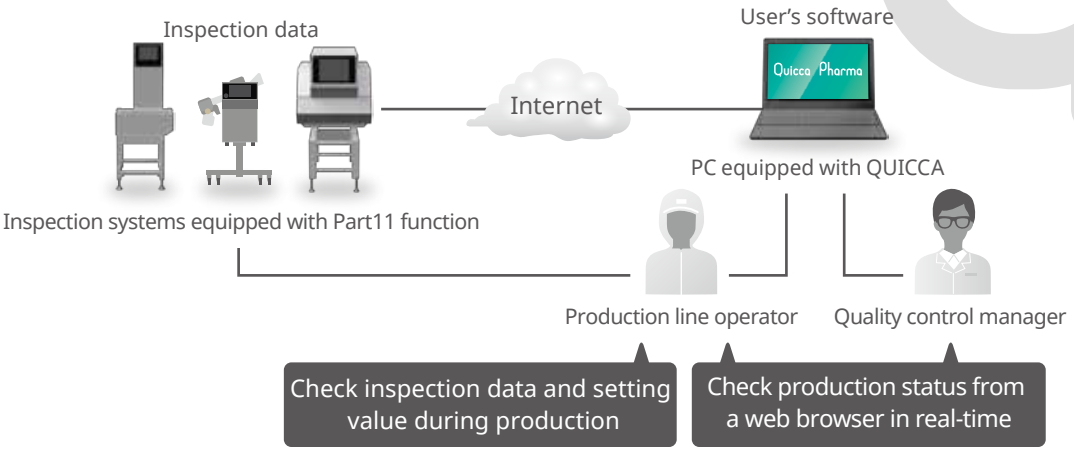


Advanced Data Integrity

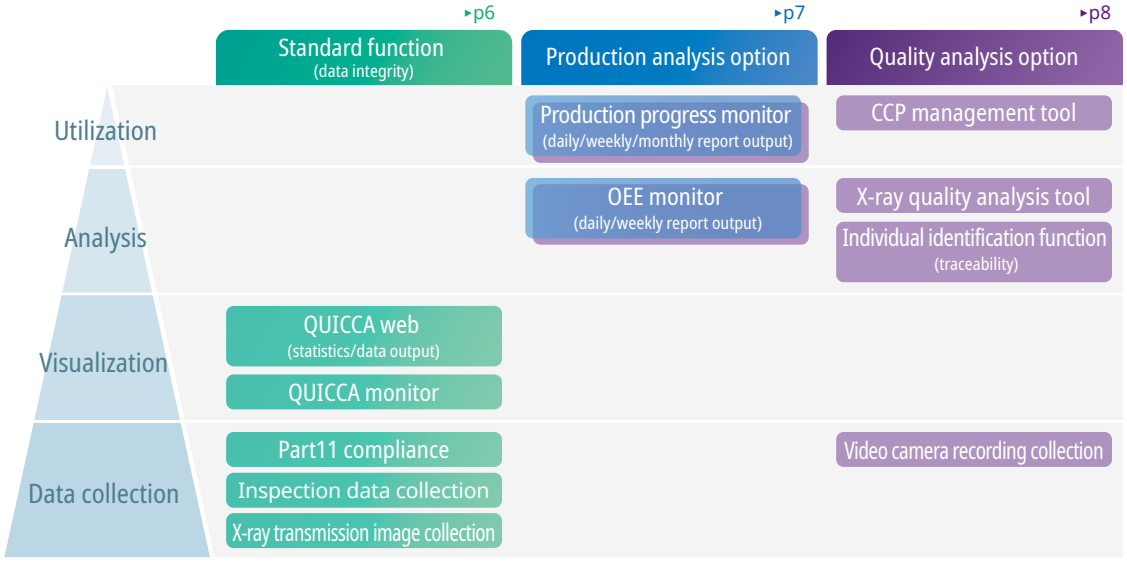
At the time of sudden system failure, data from inspection systems can be reloaded after the recovery, preventing data loss. QUICCA Pharma ensures that critical data such as statistical data and audit trail records are in place without contradiction after the recovery.

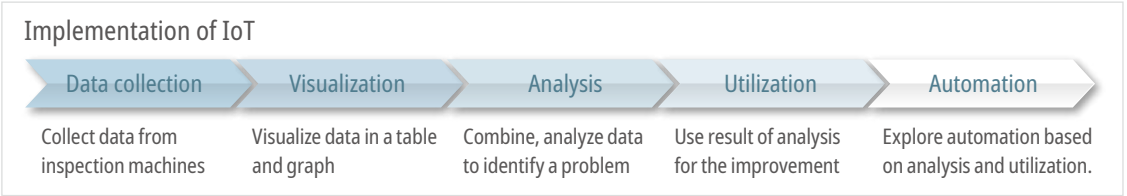
QUICCA Pharma System Summary

QUICCA Pharma is the overall quality management and quality control system for inspection equipment, providing visualization of inspection system status, production data, and quality analysis. It works with your inspection equipment to support all aspects of production.



With a QUICCA Pharma standard package, the operation status of each inspection system, and statistical information can be viewed at a glance. All the electronic data can be output into the file. Production Analysis Option allows you to visualize production progress and perform OEE (Overall Equipment Effectiveness) analysis. Quality Analysis Option includes traceability management function using individual identification codes, CCP management of inspection machines, and analysis of X-ray transmission images.





Standard Function

QUICCA Web

Production Overview Screen showing: Conveyor on/off, production counts, and reject counts. Production information can be viewed from multiple locations simultaneously.

Inspection data can be easily searched by period, inspection equipment (a serial number), and product name. Electronic reports can be quickly generated in PDF format. enabling paperless reporting of inspection data.

Statistical report

Information					
Type	Check Weigher		Start Time	2020-09-18 09:00:00	
Machine Name	CW Machine No.1		End Time	2020-09-18 12:00:00	
Line	0001	03	Line name	Packaging process No.1	
Prod No.	001		Prod Name	Headache medicine	
Lot No.	LotNo1		Statistical method	All	
Statistical data					
Total count	2,394	pcs.	100	%	
No. of products	2,394	pcs.	100.00	%	
PASS products	2,326	pcs.	97.16	%	
+NG products	35	pcs.	1.46	%	
-NG products	33	pcs.	1.38	%	
D-Prod.	0	pcs.	0.00	%	
MDNG	0	pcs.	0.00	%	
EXNG	0	pcs.	0.00	%	
Total weight	48	kg			
Mean(X-bar)	20.00	g			
Maximum value	23	g			
Minimum value	17	g			
Dispersion	6	g			
Standard deviation	0.31	g			
reference value	20	g			
Upper limit	1	g			
Lower limit	-1	g			
Product length	100	mm			

Individual data report (1/10)

Information						
Type	Check Weigher		Start Time	2020-08-28 10:11:40		
Machine Name	KWS6003BP03		End Time	2020-08-28 10:15:59		
Line	0001	03	Line name	Line 1		
Individual data						
Total 426 (1 - 41)						
No.	Date Time	Prod No.	Prod Name	Result		Weight
1	2020-08-28 10:11:40	011	---	PASS		27.24 g
2	2020-08-28 10:11:41	011	Tablet	PASS		22.80 g
3	2020-08-28 10:11:42	011	Tablet	PASS		24.13 g
4	2020-08-28 10:11:43	011	Tablet	PASS		24.82 g
5	2020-08-28 10:11:43	011	Tablet	PASS		25.26 g
6	2020-08-28 10:11:44	011	Tablet	PASS		23.95 g
7	2020-08-28 10:11:44	011	Tablet	PASS		26.78 g
8	2020-08-28 10:11:45	011	Tablet	PASS		22.27 g
9	2020-08-28 10:11:45	011	Tablet	PASS		24.81 g
10	2020-08-28 10:11:46	011	Tablet	PASS		25.58 g
11	2020-08-28 10:11:47	011	Tablet	PASS		25.10 g
12	2020-08-28 10:11:47	011	Tablet	PASS		24.81 g
13	2020-08-28 10:11:48	011	Tablet	PASS		23.87 g
14	2020-08-28 10:11:49	011	Tablet	PASS		25.34 g
15	2020-08-28 10:11:49	011	Tablet	PASS		26.02 g
16	2020-08-28 10:11:50	011	Tablet	PASS		25.74 g
17	2020-08-28 10:11:50	011	Tablet	PASS		23.91 g
18	2020-08-28 10:11:51	011	Tablet	PASS		24.35 g

QUICCA Monitor

Individual users can customize the display with the information they require. Plant manager, quality manager, and production manager have access to critical production/quality data simultaneously from multiple locations, real-time and informed communication is now possible. This can help make quick decisions before a small problem becomes a big problem, enhancing productivity and reducing prime cost.

Production Analysis Option

Production Progress Monitor

Production line status can be viewed in a lot or a time unit on a screen, which enables monitoring of momentary stoppages and production delays. Any deviation between the plan and the actual result can be quickly observed to optimize production plan. Accumulating such data will be useful for the future equipment planning or unexpected plan change in production amount.

OEE Monitor

OEE (Overall Equipment Effectiveness) is an index for measuring manufacturing productivity. It is calculated by multiplying the three OEE factors: Availability, Pefromance, and Quality. The index allows you to assess the efficiency of the production process. OEE can help you gain an accurate understanding of overall production efficiency and the details behind the numbers so you can focus resources and attention where they are needed most.

The hourly trend in each indicator is displayed in a graph.

Analyze causes of productivity loss for improvement

- Availability: Slow start/Take time for changeover or adjustment
- Performance: Occurrence of momentary stoppage/different operator/low performance due to the aging of equipment
- Quality: Incorrect setting of the inspection system/quality issue by changing a supplier of raw materials.

Quality Analysis Option

Quality Analysis Tool for X-ray Inspection System

Supports operations to prevent defects from reaching your customers.

- Rejected product images are automatically extracted for a final check prior to shipment.
- Various inspection settings help reduce the risk of contaminated product reaching consumers.
- View images both before and after a rejected product to confirm all contaminants are removed.

CCP Management Tool

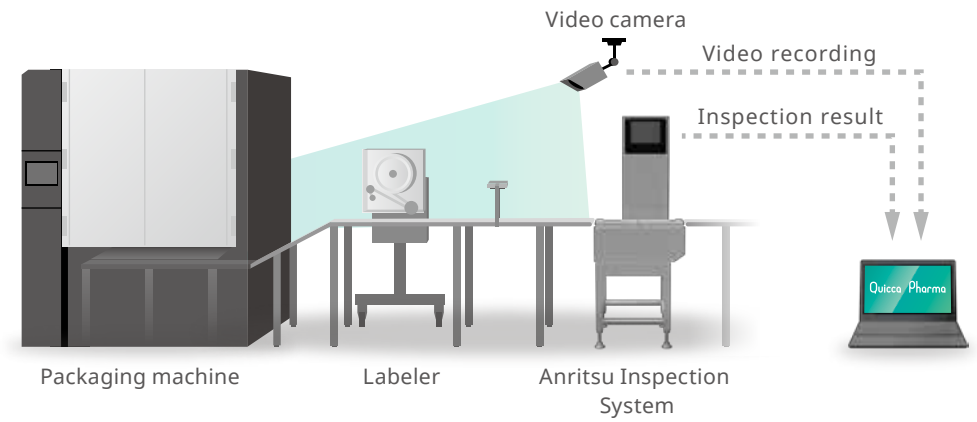
Operation checks and the associated product name, time/date, and the operator's ID who performed the check are automatically recorded. If any step is omitted or not performed properly, QUICCA's lookout functions halt system operation thereby ensuring operation is only allowed if the checks are completed. QUICCA can also issue a report showing the product inspection has been performed according to the HACCP program.

Traceability of Inspection Data

Individual ID information for each product is associated with inspection data from an x-ray system and a checkweigher and recorded in one centralized location. By scanning ID codes printed on each product, the inspection history of a specific product can be extracted instantly to confirm there was no problem in the manufacturing process. This function ensures fast and reliable response to product quality complaints.

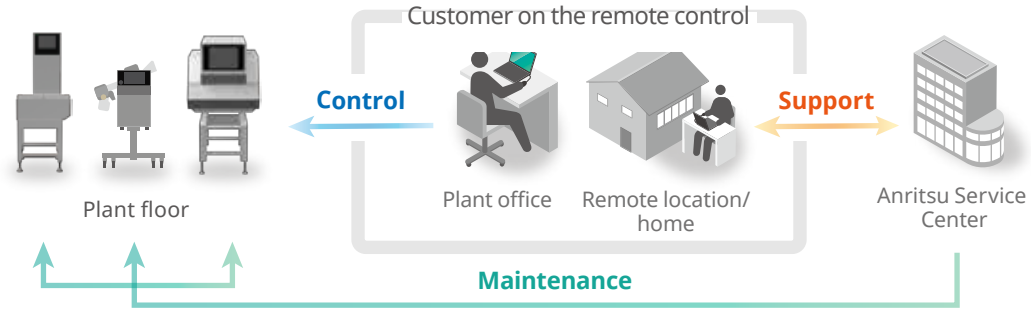
Video Recording

You can quickly respond to a complaint from a customer by checking inspection data as well as videos of manufacturing. This function also helps analyze a factor of the decrease in productivity such as momentary stoppages and production delays.



Operational Support
Anritsu Remote Solution

Our remote technical support provides monitoring of inspection systems and recovery of machine failure. Our customers can access fast and reliable remote support service from anywhere at any time.



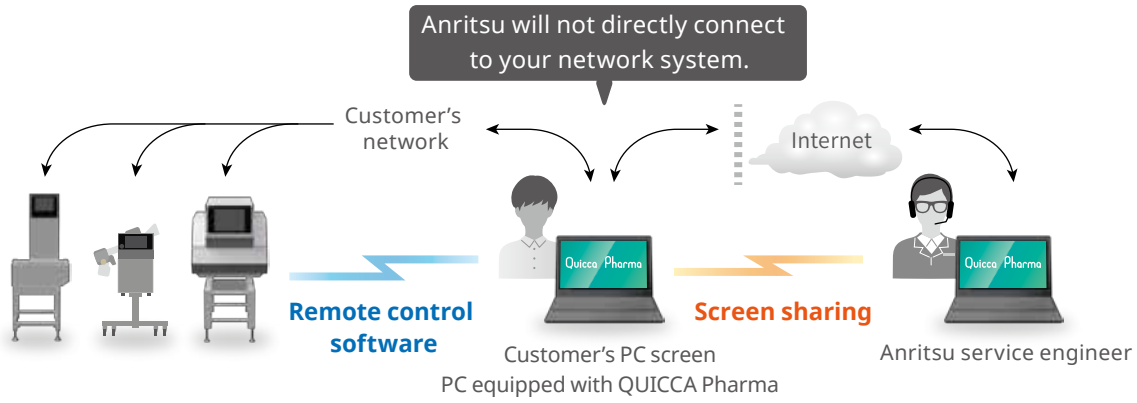
Remote Control

A remote control is available to inspection systems used by authenticated customers. At the time of error occurrence, our technicians can handle an error and check conditions such as the settings and inspection sensitivity by remote control. From office and remote location, a user can verify production progress vs. production plan, and analyze productivity and data on the production line. This can help improve work efficiency and adopt teleworking.

Remote Support/Remote Maintenance

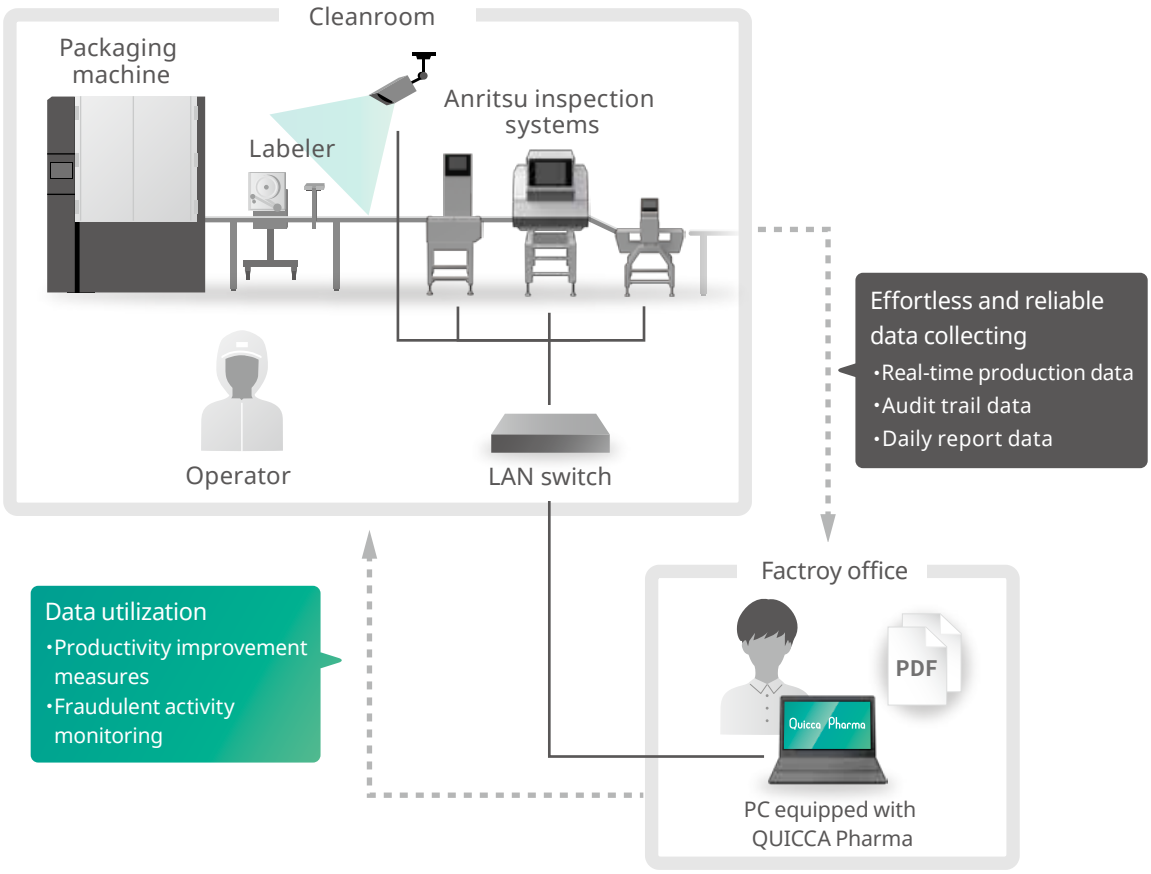
For authenticated customers, our experienced engineers offer technical support ranging from operating instructions to recovering from errors through online call. This will minimize downtime on the production line and enhance productivity. History data diagnosis can identify the possible cause of an error to improve performance. Our engineers can remotely check the current condition of inspection equipment such as power supply, voltage value, battery status, coil balance, output alarm, etc., eliminating the need for attendance of customers so that the overall running cost of the inspection system can be reduced.

Connection Method



QUICCA Pharma: Application Examples

Single inspection line:



QUICCA Pharma can achieve:

Real-time data collection

Information can be viewed on a single screen without looking at operation screen on each machine, reducing labor for data collection.

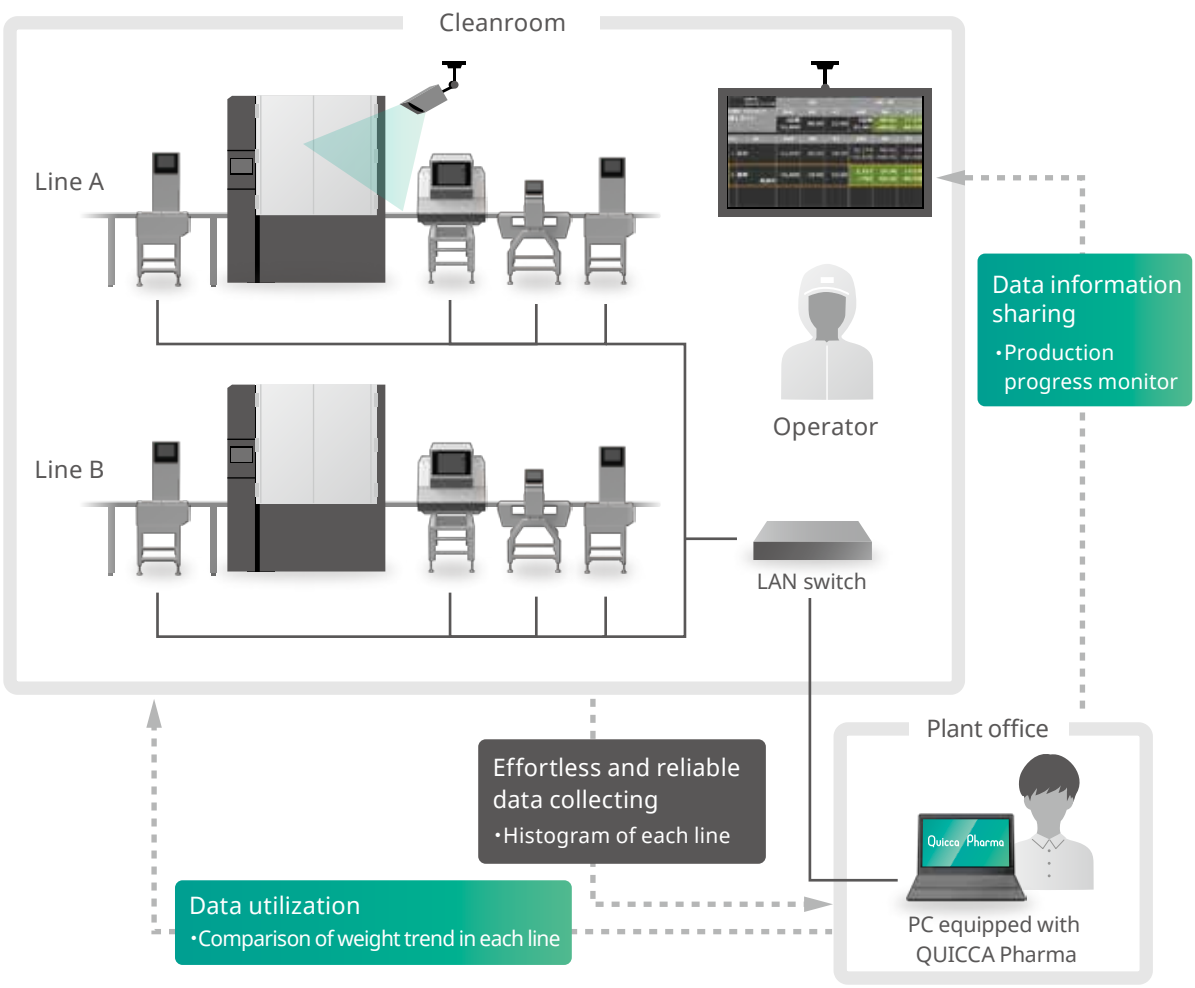
Record audit trail for smooth implementation of 21 CFR Part11

Audit trail records can be viewed and transmitted as a report from PC on the factory floor and offices. It eliminates the need for a USB flash in a cleanroom.

Enhance productivity

Production status searched by date, inspection equipment, lot number, product name, etc. can be exported to a file format. It enables daily reports to go paperless in your factory. Production data can be used to take necessary measures for the improvement of productivity.

Multiple lines:



QUICCA Pharma can achieve:

Cost reduction

Histogram in each line can be viewed on a screen at once.
The difference in the filling amount on each line can be checked immediately, preventing errors before they happen.

Prompt information sharing

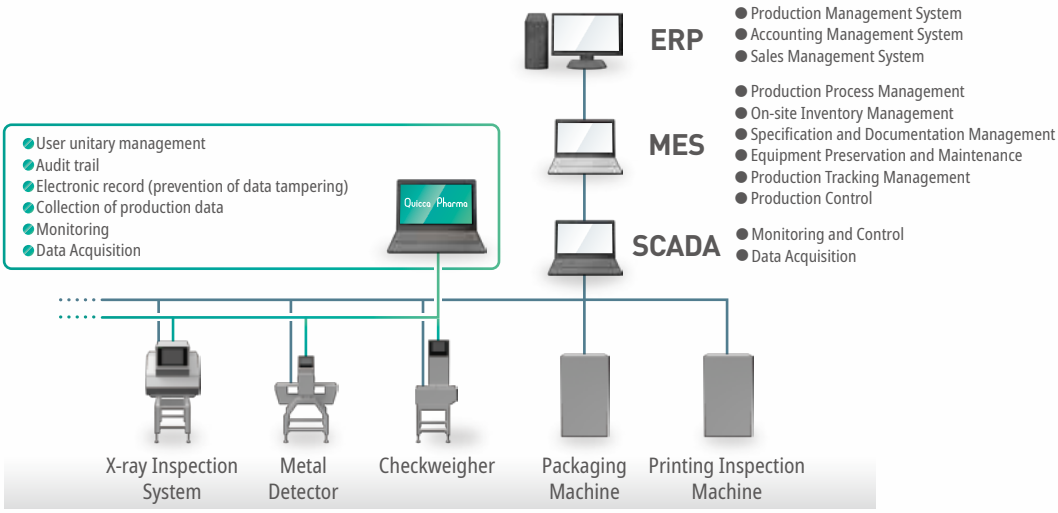
The QUICCA Pharma software can be used as a communication tool to share the real-time information on each line. It helps increase operator awareness of production efficiency on the production lines.

Construction of Plant Network

QUICCA Pharma provides visualization of inspection system status, production data, and quality analysis. Installation is simple and inexpensive.
Detailed quality analysis is difficult to manage with enterprise resource planning (ERP) and manufacturing execution systems (MES). Even if ERP and MES are already in place, QUICCA Pharma can achieve a higher degree of quality assurance.

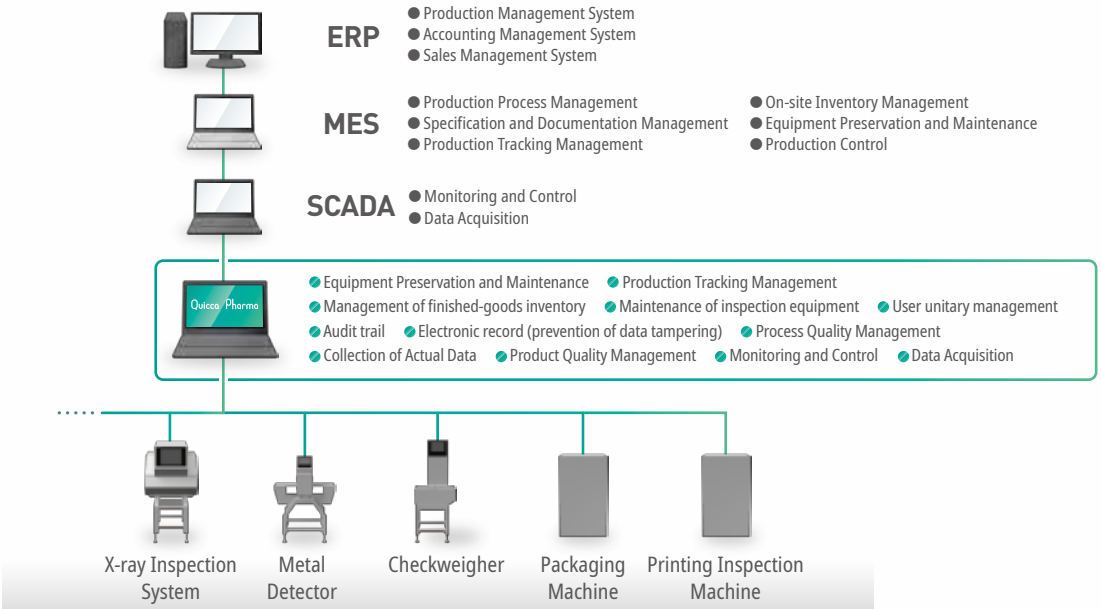
Connection pattern 1

Production and quality control provided by QUICCA Pharma's standard functions



Connection pattern 2

All key production equipment is connected to QUICCA Pharma with Production Analysis and Quality Analysis options.



System Requirements

Item	Notes	Form supplied
PC (PC, server)	PC for QUICCA Pharma installation	USER
LAN cable	Category 5e or higher. Gigabyte and Ethernet compatible products recommended.	
LAN switch (switching hub)	Required when connecting multiple equipment. Gigabyte and Ethernet compatible products recommended.	
Cable installation and wiring work	Required for connecting PC, LAN switch, etc.	
HDD for back-up (NAS, USB-HDD)	Required when performing data back-up.	
External HDD for expansion* (NAS, USB-HDD)	Required when PC HDD capacity is insufficient. USB3.0 connection compatible products recommended.	
QUICCA Pharma	Separate connection licenses are required according to the number of machines connected.	ANRITSU
Ethernet unit	Required depending on equipment to be connected.	
Equipment	X-ray inspection system, metal detector, checkweigher	

*When implementing user authentication of an inspection system by a user's server, Active Directory Service is required in a user's server.
*HDD (hard disk) is a consumable product. Subscription to manufacturer long-term warranty and on-site maintenance is recommended.

Specifications

QUICCA Pharma

Maximum recording capacity*	3000 products/min (all lines) 1,500 items/min (when only X-ray inspection system is connected for recording of transmitted images) When only X-ray inspection system is connected for recording of transmitted images, storage capacity for the X-ray machine is calculated as double.
Maximum number of recordable data	Depends on free disk space on PC. Maximum 4 million data/day 1 million to 4 million data/1 GB (Individual data, Statistics data, History data) 10,000 to 30,000 data/1 GB (image data) Data can be saved on multiple hard drives such as NAS

*The maximum number of connectable machines and recording capacity varies depending on specification of PC and network configuration.
*When displaying and recording all of the images taken by an x-ray inspection system, processing capacity of image recording vary depending on the operating system. Server OS is required when more than four x-ray systems are connected to a PC. Please contact Anritsu sales representatives for latest supported operating system.

Computer operating environment

■ Server

OS	Windows Server 2012/R2 (Standard/Datacenter/Essentials/Foundation) Windows 10 (Pro/Enterprise) Windows Server 2016 (Standard/Datacenter/Essentials) Windoes Server 2019 (Standard/Datacenter/Essentials)
CPU	Intel Core i3 Processor 2.80 GHz or higher
Memory	8 GB or higher
HDD	1 GB or more free disk space for installation in addition to that required for data saving When using external HDD for continuous recording, HDD with USB 3.0 is recommended.
Display	1024 × 768 or higher
LAN	Ethernet (100BASE-TX, 1000BASE-T)
Required browser	Google Chrome, Microsoft Internet Explorer

*Higher performance is required for optimal use.

■ Client

OS	Windows 10 (Pro/Enterprise)
CPU	Intel Core i3 Processor 2.80 GHz or higher
Memory	4 GB or higher
HDD	Depends on functions used. 100 MB or more available capacity for installation
Display	1024 × 768 or higher
LAN	Ethernet (100BASE-TX, 1000BASE-T) or wireless LAN connection
Required browser	Google Chrome

Pharmaceutical Quality Assurance based on GMP

We offer a wide range of inspection solutions including dynamic weighing, contaminant and shape detection for the pharmaceutical manufacturing and packaging process.

Filling control/Weight check

Seal check/Missing tablet check

Tablets

Capsules

Sachets / Sticks

Tubes

Bottles / Cans

Pharmaceutical Metal Detector

Capsule Checkweigher

*Non-conforming to CE marking

Built-In Multi-Lane Weighing System

Pharmaceutical X-ray Inspection System

Multi-Lane Checkweigher

Aerosol Inhaler Checkweigher

*Non-conforming to CE marking

Small Bottle Checkweigher

*Non-conforming to CE marking

Supporting CSV guidelines :

Validation support

Anritsu also provides IQ/OQ checklists and on-site support during PQ process.

Supported by Anritsu

Specifications required	DQ	FAT	IQ	OQ	PQ	Completed book	PV
	Plan : Estimated product specifications Report : Specifications for approval	Plan : Report	IQ Checklist	OQ Checklist	On-site support	Submit documents based on specifications required	

Missing blister pack check

Missing insert check (magnetic ink)

Missing pack check

Missing carton check

SSV-h Series Checkweigher conforming to CFR 21 Part 11

*MID approval

M Series Metal Detector

*Non-conforming to CE marking

SSV-h Series Checkweigher

*MID approval

Case Checkweigher

*Non-conforming to CE marking

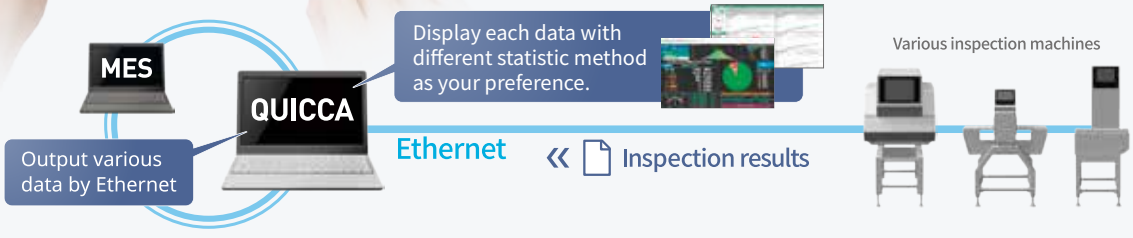
Quicca Pharma

Overall Quality Management and Control System for Pharmaceutical

Support making good use of data by various CFR 21 Part 11 complied functions.

Delivering Data Integrity as specified by CFR 21 Part 11 by utilizing the data from the machine connected to the network.

- User Authentication Management
  All user access is managed centrally.
- Audit Trail
  The history of operations and actions related to production and results of operation check are recorded and displayed in list-view style for easy and quick view.
- Production Analysis
  Production progress monitor and Overall Equipment Effectiveness (OEE) can be viewed in real time.
- Quality Analysis
  Statistic data and individual data are recorded via Ethernet.



Anritsu envision : ensure

ISO14001 CERTIFICATE No.JQA-EM0210
ISO 9001 CERTIFICATE No.JQA-0316

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- Some products shown in this catalog may not be available in your country or region. Contact our sales representatives for details.
- To ensure proper operation, read the Operation Manual before using the machine.
- In addition to daily inspection, an annual maintenance check should be carried out.

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